

Patient Consent and the Commercialization of Lab Data

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Every year, commercial testing labs earn millions of dollars from selling the anonymized results of blood, urine, tissue, and other tests with almost no public scrutiny or debate.² Few outside the industry know anything about this trade, and lab workers are often in the dark as well.

When I tell people about the growing commercial trade in anonymized patient data from sources including electronic health records, insurance claims data, and prescriptions, the sale of lab data from companies such as Quest and LabCorp sparks the greatest surprise and concern. Discussing the secondary use of data unrelated to the direct treatment of the tested patient also makes labs and their data mining clients uneasy. Many prefer to avoid any substantive discussion of the tradeoffs between advancing scientific knowledge by sharing data and protecting patient privacy.

LabCorp provides a good example of such reticence. I unsuccessfully tried to contact LabCorp's CEO three times in 2015 while researching my latest book (*1*) and another two times in 2016 for this article.³ When asked whether LabCorp shares anonymized data with outside companies, and, if so, under what circumstances, privacy officer Don Luu responded: "LabCorp would disclose de-identifiable information to business associates for various purposes related to its business and operations."⁴ After I asked for more clarity Luu acknowledged such trade: "LabCorp would share de-identified information

outside of its organization as it is permitted by the HIPAA Rules."⁵

I wrote LabCorp again regarding this article in *Clinical Chemistry*, and it took a few weeks to receive written responses from the company's chief information officer Lance Berberian. "The use of de-identified and aggregated patient data is a long-standing, widely acknowledged practice that leads to better patient outcomes," he wrote. "That data includes information derived from diagnostic results (including laboratory tests), prescribing information and claims and payment data. LabCorp, like many other healthcare service providers, has used data in this way for over a decade."

"We believe that any requirement for further disclosure or consent for the use of such de-identified data could have a significantly harmful effect on the advancement of healthcare knowledge by introducing gaps and biases into the data set if the deidentified data no longer represents a random, wide range of patients."⁶

Does Anonymized Data Still Belong to an Individual?

Tor Constantino, spokesman for the largest medical data miner, QuintilesIMS, said his firm obtained such information from middlemen companies that link health care providers with diagnostic labs. When I asked if patients should have a say in sharing their data, he wrote: "The underlying assumption in your question is inaccurate. Anonymous data does not belong to an individual because it is not identified with a specific individual."

"Treating anonymous data in the same manner as identified data will add costs to healthcare, reduce the availability of information to save lives and fail to provide any additional privacy protections to consumers."⁷

Quest Diagnostics CEO Steve Rusckowski told me the company wanted to help improve health care and so Quest under his leadership started sharing anonymized results a few years ago. "This industry and specifically this

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² Dermot Shorten, Quest's vice president of strategy and ventures, said his company earns in the low single digit millions a year from such sales. Interview with author, August 24, 2015. This figure is augmented by other laboratories selling data such as LabCorp.

³ Because of the paucity of public information about the trade in laboratory data, the author has necessarily turned to present and former company officials for details.

⁴ Don Luu, initial e-mail to author, Sept. 15, 2015.

⁵ Don Luu, second e-mail to author, Sept. 15, 2015.

⁶ Lance Berberian quotes provided to author via e-mail by LabCorp's vice president of corporate communications, Donald Von Hagen, July 1, 2016.

⁷ E-mail to author, Jun 27, 2016. Constantino also said hundreds of medical articles had relied on IMS data, some of which are listed on the company's website at <https://perma.cc/2PE7-5Z38>.

company has an incredible impact on health care already and could have more of an impact on health care," he said. "If you look at lab data, it is two percent of health care cost . . . but 70 percent of medical decisions are made on benefit of that lab diagnostic data."⁸

Yet he was unsure whether customers could opt out of anonymized sharing. Initially he said Quest offered such an option, but after our conversation he wrote back to say they did not as the HIPAA rules on medical data did not require it.

One startup buying Quest and LabCorp data is Medivo in New York, and naturally enough, its executives are bullish on the research value of such information.⁹ "You kind of combine that with some of the other data sets that are readily available out there and all of a sudden you have a much better picture of disease and the progression of disease," said co-founder Jason Bhan.

Even though researchers may gain insights from the commercialization of blood and other test results, many companies, including diagnostic imaging chain Alliance HealthCare Services¹⁰ and LifeLabs in Canada, do not sell patient data. "There is a very strong cultural anchor in this country around ownership of my personal information," said LifeLabs CEO Sue Paish, whose company performs 100 million tests a year.¹¹

She said many patients expect that data about them would only be used for their treatment. "It's about my body, it's about me," she added. "I'm not sure that any company that has my data should be able to make money from it."

The difficulty in keeping anonymized data protected against re-identification, especially as genetic testing grows more commonplace, is another concern. The more information data miners aggregate into patient dossiers, the greater the possibility of re-identification, especially as computing power increases.¹² Such information could be exploited to target medical marketing, deny life

insurance or bank loans, embarrass someone, or steal an identity to obtain medical services.

Empower Patients through Choice

Such risks are among the reasons that the US government should extend HIPAA-style protections to anonymized information about patients. Another reason to put patients in control: If the public does not expect blood tests and other data about them to be a commercial product, their trust in the health care system may be shaken when they learn what is really going on. Some information can be deeply personal, even if the name is removed.

Whether patient choice should come via an opt-in or opt-out program, how to administer such a system, and when public safety overrides patient empowerment (such as during epidemics), are all issues that should be openly debated. Yet dispassionate discussion is difficult because many companies trading anonymized patient information are not transparent about their activities. Some fear transparency will lead to restrictions in the trade. Others believe patients will not understand the subtleties of anonymized data. Precisely because the topic is complicated and nuanced, we need to actively and publicly discuss how to best advance science while preserving patient privacy.

Keeping patients in the dark about what happens after blood flows into a vial or urine fills a cup is no way to advance this dialogue. Showing true leadership on the issue means not hiding behind the coded language of interminable privacy policies or public relations obfuscation. Many patients will gladly share information to help science. But give them a say in when and how the sharing takes place.

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1. Tanner A. *Our Bodies, Our Data: How Companies Make Billions Selling Our Medical Records*. Boston: Beacon Press; 2017.

⁸ Interview with author, Sept. 11, 2015.

⁹ Interview with author, June 15, 2015, and June 20, 2016.

¹⁰ CEO Tom Tomlinson, interview with author, June 27, 2016.

¹¹ Interview with author, June 22, 2016.

¹² For more information on reidentifying anonymized medical records, see the writings of Latanya Sweeney, the founder of Harvard's Data Privacy Lab. "[S]ociety has experienced an explosion in the amount of data collected on individuals, challenging HIPAA's 1990s styled protection," she writes in "Patient Privacy Risks in U.S. Supreme Court Case Sorrell v. IMS Health Inc., Response to Amici Brief of El Emam and Yakowitz," working paper 1027-1015B, Data Privacy Lab, Harvard University, Cambridge, MA, 2011, archived at <http://perma.cc/UR5K-JXZE>.